MAY 1 6 2002 K021396

510(k) Summary

1.0 Submitter:

Name:	WRP Specialty Products Sdn Bhd.
Address:	Lot 11, Jalan 2, Kawasan Perushaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, MALAYSIA
Phone No.:	+60 3 8706 9788
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Date of Summary Prepared: 30 APR 2002

2.0 Contact Person:

Name:	V. Nadarajan
Phone No.:	+60 3 8706 9788
Fax No.:	+60 3 8706 5020

3.0 Name of the device:

Proprietary or Trade Name:	1)	Dermagrip, and
	2)	Multiple or Customer's Trade Name
Classification Name :	Patient Examination Gloves (per 21 CFR 880.6250)	
Device Name :	Powder Free Purple Nitrile Examination Gloves, Non-Sterile	

4.0 Identification of The Legally Marketed Device:

Class I patient examination gloves, 80LZA, powder free, that meets all the requirements of ASTM standard D 6319 – 00a^{E1} and FDA 21 CFR 800.20.

5.0 Description of The Device:

The Powder Free Purple Nitrile Examination Gloves, Non Sterile meets all the requirements of ASTM standard D 6319 – 00a^{E1} and FDA 21 CFR 800.20.

6.0 Intended Use of the Device:

The patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

7.0 Summary of The Technological Characteristics of The Device:

The Powder Free Purple Nitrile Examination Gloves, Non Sterile is summarized with the following technological characteristics compared to ASTM or equivalent standards.

Characteristics	Standards	Device Performance
Dimensions	*ASTM D 6319 – 00a^{E1}*	*Meets*
Physical Properties	*ASTM D 6319 – 00a^{E1}*	*Meets*
Freedom from pinholes	*ASTM D 6319 – 00a^{E1}*	*Meets*
	FDA 21 CFR 800.20	
Powder-Free	*ASTM D 6124 – 01*	*< 2 mg/glove*
Biocompatability	*Primary Skin Irritation in Rabbits*	*Passes (Not a primary skin irritant)*
	Dermal Sensitization	*Passes (Not a contact sensitizer)*

8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above.

9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

10.0 Conclusion

It can be concluded that the Powder Free Purple Nitrile Examination Gloves, Non Sterile will perform according to the glove performance standards referenced referenced in Section 7 above and meet ASTM standards, and FDA requirements for water leak test on pinhole AQL. Consequently, this device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2002

Mr. V. Nadarajan
Manager, QA/RA
Lot 11, Jalan 2, Kawasan Perusahaan
Bandar Baru Salak Tinggi,
43900 Sepang
Selangor Darul Ehsan,
MALAYSIA

Re: K021396
Trade/Device Name: Dermagrip and Multiple Powder Free Purple Nitrile Examination Gloves
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: April 30, 2002
Received: May 2, 2002

Dear Mr. V. Nadarajan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE

Applicant: WRP Specialty Products Sdn Bhd

510(k) Number (if known): K021396

Device Name: POWDER FREE PURPLE NITRILE EXAMINATION GLOVES, NON STERILE

Indications For Use:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Concurrence of CDRH, Office of Device Evaluation (ODE)

SKB for Chen

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021396

Prescription Use _____ OR Over-The-Counter _____
(Per 21 CFR 801.109)